REMARKS

Rejection under 35 U.S.C. § 102(b)

Claim 46 is rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,555,618 (hereinafter referred to as "Winkler").

Applicant has amended claims 46 and 56 to recite --discontinuity-- in lieu of "boundary" for the purpose of providing greater clarity to the claim language. Also, Applicant has amended claims 46 and 56 to recite that there is no inter-layer discontinuity "along a substantial length of the neuromodulation lead." The amendments are fully supported by the original application. No new matter has been entered.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Applicant respectfully submits that the applied reference does not satisfy these criteria.

Claim 46 recites:

> a solid matrix of fused insulative material surrounding and electrically insulating each of the first and second plurality of conductors thereby forming a lead body, wherein the solid matrix of materials (i) retains each of the first plurality of conductors at the substantially same first radial depth in the lead body, (ii) retains the second plurality of conductors at the substantially same second radial depth in the lead body, the second radial depth being underneath the first radial depth, and (iii) retains each conductor of the first and second plurality of conductors at a prescribed distance from adjacent conductors, wherein the solid matrix of fused insulative material does not possess an inter-layer discontinuity between the first and second radial depths along a substantial length of the neuromodulation lead.

In regard to Winkler, the rejection states that "the materials are in a molten state since they are shore D hardness of 75...which requires heating for embedding the wires...Such heating would tend to fuse the two layers of polyurethane together." Office Action, page 3.

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *See* MPEP § 2112 citing *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Applicant respectfully submits that the rejection has not satisfied the requirements for a theory of inherency. Specifically, there is no factual basis why the respective layers of Winkler are necessarily fused together such that there is no "inter-layer discontinuity between the first and second radial depths along a substantial length of the neuromodulation lead." In fact, Winkler explicitly depicts the opposite of the asserted inherent characteristic. As shown in FIGURES 10 and 11 of Winkler, there is a clear discontinuity and separation between layers 44a and 44b. Thus, the various layers of Winkler are unquestionably structurally distinct and separate layers and, hence, there is no "solid matrix" that "does not possess an inter-layer boundary between the first and second radial depths" in Winkler as recited by claim 46.

Applicant additionally notes that Winkler merely discloses a fabrication process for its stimulation lead in which layers 44a and 44b are generated by over-extruding a previously fabricated layer with an exterior layer of polymer. Over-extrusion does not inherently create a fused matrix of material with no "inter-layer discontinuity between the first and second radial depths along a substantial length of the neuromodulation lead." Applicant refers the Examiner to FIGURES 6 and of 7 of the present application where over-extrusion is applied and the accompanying discussion in the specification. The over-extrusion, by itself, does not create a fused matrix as claimed. *See* paragraphs [0070]-[0073] of the application. Instead, it is the application of shrink-wrap and heat processing that creates the fused matrix. *See* paragraphs [0074] and [0075] of the application.

Accordingly, there is ample evidence in the record that refutes the inherency argument proffered by the rejection under Winkler.

Applicant respectfully submits that claim 46 is not anticipated by Winkler and requests the Examiner to withdraw the rejection.

Rejections under 35 U.S.C. § 103(a)

Claims 46-55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Winkler (alone) or alternatively in view of U.S. Patent No. 5,334,169 (hereinafter referred to as "Brown").

Claims 56-65 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Winkler, (alone) or alternatively in view of Brown, in further view of U.S. Patent No. 5,733,322 (hereinafter referred to as "Starkebaum").

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP § 2143.

Applicant respectfully submits that the applied references do not satisfy these criteria.

Independent claims 46 and 56 recite:

> a solid matrix of fused insulative material surrounding and electrically insulating each of the first and second plurality of conductors thereby forming a lead body, wherein the solid matrix of materials (i) retains each of the first plurality of conductors at the substantially same first radial depth in the lead body, (ii) retains the second plurality of conductors at the substantially same second radial depth in the lead body, the second radial depth being underneath the first radial depth, and (iii) retains each conductor of the first and second plurality of conductors at a prescribed distance from adjacent conductors, wherein the solid matrix of fused insulative material does not possess an inter-layer discontinuity between the first and second radial depths along a substantial length of the neuromodulation lead.

Winkler (U.S. Patent No. 5,555,618) discloses a lead that includes a plurality of layers. *See, e.g.*, FIGURE 10 of Winkler. The plurality of layers are merely produced by "extruding over" the interior layer with another previously constructed layer of plastic. Col. 10, line 60 through col. 11, line 3. In particular, the interlayer delineation can be seen in regard to layers 44a and 44b of FIGURE 10. Thus, the various layers of Winkler are unquestionably structurally distinct and separate layers and, hence, Winkler does not teach or

suggest a "solid matrix" that "does not possess an inter-layer boundary between the first and second radial depths" as recited by claims 46 and 56.

In the alternative rejection under Brown, the Office States that "Brown teaches embedding wires of opposite winding in a tubular member...to produce a monolithic layer of material." As a motivation to modify the fabrication technique of Winkler in view Brown, the Office Action states that the modification would be desirable "to prevent unwanted layer separation." Office Action, page 3.

Applicant respectfully submits that the catheter in Brown is adapted for a very different purpose than the subject matter of Winkler (and also the claimed subject matter). Because of the difference, one of ordinary skill in the art would not be motivated to utilize the co-extrusion and concurrent delivery of "reinforcement strands" of Brown for the Winkler stimulation lead.

Brown is directed to a reinforced catheter with thin monolithic walls having "reinforcing strands" spirally wound therein. *See* Abstract of Brown. The purpose of the "reinforcing strands" is to provide "circumferentially inflexibility" to allow the catheter to be "steered" through the vascular system of a patient. *See* col. 6, lines 7-16 and lines 26-30 and col. 1, lines 36-42. The reinforcing strands are integrated within the catheter walls by coextruding "from inside and outside of the strands while the material for the wall 9 is molten and fusible with the strands included in it." Col. 6, lines 30-34.

However, the "reinforcing strands" of Brown cannot be read upon the recited first or second plurality of conductors. Specifically, as seen in claims 46 and 56, each conductor of the first and second plurality of conductors are "individually electrically isolated" and are coupled to a respective electrode. Additionally, the conductors in claims 46 and 56 are maintained at prescribed distances from each other and the radial depth of the conductors are controlled. The purpose of such positional control is to maintain the electrical isolation and to facilitate electrode formation. As is known in the art, electrode formation frequently occurs by ablating (e.g., using a pulsed laser) insulative material in the lead body to expose a conductor. If the positions of the conductors are not controlled, the ablation can expose two conductors at once (e.g., when the two conductors are too close) or can create an opening

through to the lumen of the lead body (e.g., when the radial depth of a conductor is too close to the lumen). In either case, the lead body becomes unsuitable for use as a stimulation lead. Additionally, Applicant respectfully refers the Examiner to Figs. 4A-4D of Winkler as an example of electrode formation.

Winkler explicitly acknowledges the importance of maintaining the positions of the wire conductors relative to each other. Specifically, Winkler discloses that "in order to preclude accidental movement of the spaced apart plurality of wound wires prior to over-extrusion of outer layer 20 thereover, the wires 45 are helically or spirally would around the layer 44 (under roughly hand tension) so that they at least partially embed themselves within the core-covering layer 44." Col. 5, lines 60-66.

The catheter fabrication process of Brown is completely inapposite to the explicit teaching of Winkler. In Brown, the various layers of extrusion material are maintained in a "molten state" as the multiple layers of wires are fed from "wrapper" mechanisms. Specifically, Brown states that the "co-extrusion method 16 can be continued by maintaining molten heat of the catheter wall 21 and employing a second wrapper 28 for adding a second layer of reinforcement material." Col. 7, lines 47-51. Because the extrusion material is maintained in a "molten state" while wires are being embedded in the extrusion material, the wires are free to move within the molten material. Hence, according to the Brown fabrication process, there is no physical mechanism in the lead itself during the extrusion process that "precludes accidental movement" of the wires as taught by Winkler.

Thus, Winkler explicitly teaches away from the combination proffered in the Office Action and, accordingly, the combination is improper under well-accepted legal principles. *See* MPEP § 2145 citing *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

Starkebaum is merely cited in the Office Action to demonstrate that it is known to use stimulation leads with pulse generators. Starkebaum does not teach or suggest the recited characteristics of the fused insulative material, conductors, and electrodes of claims 41 and 51.

Thus, from the teachings and suggestions of the applied references (either alone or in combination), one of ordinary skill in the art would not have been motivated to arrive at the claimed subject matter of claims 46 and 56. A prima facie case of obviousness has not been established for these claims. Claims 47-55 and 57-67 respectively depend from claims 46 and 56 and a prima facie case of obviousness has not been established for these claims.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. If the Examiner believes that a telephone call would be helpful to resolve any remaining issues, the Examiner is invited to call Applicant's attorney Christopher S.L. Crawford (Reg. No. 51,586) at (972) 309-8006.

Applicant has submitted a one month extension of time fee in a separate paper. If any other fee or fee amount is due, please charge Deposit Account No. 50-3906, from which the undersigned is authorized to draw.

Dated: 9-21-2006

Respectfully submitted,

By 

Christopher S.L. Crawford
Reg. No.: 51,586
Advanced Neuromodulation Systems
6901 Preston Road
Plano, TX 75024
(972) 309-8006
(972) 526-9796 (fax)